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Re-evaluation Decision

Chlorpropham

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Re-evaluation Decision

The purpose of this Re-evaluation Decision document is to notify registrants, pesticide regulatory officials and the Canadian public that the re-evaluation of chlorpropham is now complete. After a re-evaluation of chlorpropham, Heath Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration for the sale and use in Canada of products containing chlorpropham.

On 26 March 2007, the PMRA published PACR2007-04, *Re-evaluation of Chlorpropham*, for public consultation. Appendix I summarizes the comments received during the consultation process and provides the PMRA's response to these comments.

An evaluation of available scientific information found that products containing chlorpropham do not present unacceptable risks to human health or the environment when used according to label directions. This decision is consistent with the re-evaluation decision proposed in PACR2007-04. As a condition of the continued registration of chlorpropham use, the revised label improvements, which further protect human health (Appendix II), must be included on the labels of products containing chlorpropham. Additional data are not required as a result of this re-evaluation. Registrants of products containing chlorpropham have been informed of the specific requirements affecting their product registration(s).

Any person may file a notice of objection regarding this decision on chlorpropham within 60 days from the date of publication of the Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Appendix I Comments and Responses

The PMRA received comments to PACR2007-04 and has consolidated and summarized the comments received and provides responses to the comments below:

1.0 Comment on Inhalation

The respondent disputes the PMRA's waiver of an inhalation study and has indicated that the PMRA's waiver for an inhalation assay was in error since chlorpropham solutions can be prepared for aerosol distribution.

PMRA Response:

In PACR2007-04, the PMRA had waived the requirement for an acute inhalation assay as it was of the belief that chlorpropham technical could not be prepared in a suitable manner for the purposes of toxicology studies. However, the PMRA has recently identified an acceptable acute inhalation toxicity study in rats using chlorpropham technical. The acute inhalation study indicated an LC_{50} of greater than 2.0 mg/L, or low toxicity from the inhalation route.

2.0 Comment on Atmospheric Release of Chlorpropham

The respondent considers that the PMRA's re-evaluation seriously underestimates a variety of risks because there is no mention of the significant release of chlorpropham to the outside atmosphere during the application process.

The primary concern identified by the respondent is the loss of chlorpropham to the environment during application to a storage facility. The respondent estimates that as much as 50% of the applied active ingredient is lost to the area surrounding the facility.

PMRA Response:

No monitoring data exists to support the release of chlorpropham to the atmosphere nor to confirm the deposition on surfaces within the facility.

Although indications are that less than 50% of the applied chlorpropham is deposited onto the potato pile, there is no evidence to suggest that as much as 50% is lost to the atmosphere. It is assumed that some particles would accumulate on the building surfaces (as demonstrated by the need to regularly clean fans, plenums, etc.) and some would be broken down or destroyed during the typical application and ventilation practices. Of the remaining chlorpropham, ventilation to the outside atmosphere would obviously dilute the concentration of suspended chlorpropham particles considerably. No health effect incident reports were found in either the U.S. or Canada related to occupational or bystander chlorpropham exposure.

Both long-term storage facilities using aerosol foggers and smaller facilities using liquid spray conveyor belts were assessed by the PMRA. Those workers in the smaller facility incur more exposure than any other individuals associated with the application of chlorpropham to storage potatoes.

The occupational risk assessment assumes that a worker mixing/loading and applying chlorpropham at the maximum application rate would be exposed to chlorpropham for eight hours a day. These assumptions are conservative and likely result in an overestimation of actual exposure. Margins of exposure (MOEs) calculated for these workers exceed the established target and are not of concern.

Given that the amount of chlorpropham that is displaced to the atmosphere is likely to be considerably less than 50% of the label rate, that any chlorpropham particles available to respiration/dermal contact would be greatly diluted by the atmosphere, and that the risk assessment for occupational workers does not exceed the Agency's level of concern (8 hours/day at the maximum label rate), it is highly unlikely that any incidental bystander exposure would be of concern to the Agency. Following any application, the remaining chlorpropham that is released to the atmosphere and thus diluted would result in far less exposure than that incurred by storage facility workers. No further residential risk assessment is required to assess chlorpropham exposure to individuals within the vicinity of the facilities.

3.0 Comment on Application Rate Differences

The respondent indicated the Canadian application rate for potato storage is approximately double that of the U.S.

PMRA Response:

Current label restrictions list the maximum Canadian rate as 0.0375 kg a.i./tonne of potatoes, and the maximum American label rate appears to be 0.026 kg a.i./tonne. The higher rate, as suggested by the respondent, is assumed to be due to the difference in industrial technologies. While the facilities using the lower rates are apparently equipped with more efficient technology, the current maximum rate in Canada does not pose an unacceptable risk to facility workers, and as such, the PMRA will not recommend that Canadian storage facilities be required to adopt new equipment and practices on the basis of occupational risk.

4.0 Comment on Re-entry Activities for Potato Storage Facilities

The respondent suggested that the risk assessment consider using "visible aerosol" as a primary criterion for determining re-entry into a space.

PMRA Response:

The current application practices in large potato storage facilities prohibit re-entry into the potato storage chamber following an application until adequate ventilation (2–4 hours minimum) has been completed. There are also strict recommendations for personal protective equipment (PPE) should the need arise for an early re-entry activity (e.g. repairs).

The respondent has voiced concerns that current label recommendations are inadequate in controlling re-entry. The primary concern is respiration of suspended particles, and to a lesser extent, contact with treated surfaces.

According to all sources, re-entry activities are rare and carefully conducted with full PPE, bearing in mind the low oxygen environment. When the label precautions are followed, exposure due to re-entry is minimal and the risk to the worker is negligible. It is assumed that following adequate ventilation, no visible aerosol would remain. However, to clarify, the PMRA will modify the re-entry statements on labels for potato storage facilities to include the following:

"Do not allow entry into treated areas (to attend to fans, etc.) until after two (2) hours of mechanical ventilation (fans should circulate outside air) or four (4) hours of passive ventilation (windows, vents and doors should be opened). If visible aerosol remains after these periods, do not enter until the aerosol has settled."

Appendix II Revised Label Amendments for Products Containing Chlorpropham

NOTE: This appendix does not identify all label requirements for individual end-use products such as first aid statements, disposal statements, precautionary statements and supplementary personal protective equipment that may be required. Additional information on labels for currently registered products should not be removed unless it contradicts information in this appendix.

Canadian end-use product labels must be amended to include the following to further protect human health and the environment.

PRIMARY PANEL:

Remove the following statement that, as a result of re-evaluation, is no longer applicable:

> "WARNING: Safety data and registration of this product are under review. Directions for use and cautionary statements should be carefully followed."

PRECAUTIONS:

Remove the following statement from the label:

> "Do not feed treated potatoes to livestock."

For all chlorpropham products, the following statements must be added to the label.

TOXICOLOGICAL INFORMATION:

> Overexposure to chlorpropham may result in methemoglobinemia.

PROTECTIVE CLOTHING AND EQUIPMENT:

Personal Protective Equipment:

> For mixing and loading, wear cotton coveralls and chemical-resistant gloves.

DIRECTIONS FOR USE:

For Commercial Class products, the application rates must be expressed as volume or weight of product per 25, 50 or 100 tonnes of potatoes.

For all chlorpropham products used in packing plants and applied on conveyor belts, the following statements must be added to the label.

PROTECTIVE CLOTHING AND EQUIPMENT:

Engineering Controls:

Installation of a shield around the conveyor belt is required to prevent spray mist drifting.

Personal Protective Equipment:

For application using the screened sprayer systems and for bagging/packing potatoes, wear cotton coveralls and chemical-resistant gloves.

For all chlorpropham products used in potato storage facilities using fogger systems, the following statements must be added to the label.

PROTECTIVE CLOTHING AND EQUIPMENT:

Personal Protective Equipment:

For all re-entry tasks (including cleaning) prior to the completion of ventilation, wear chemical-resistant coveralls over a long-sleeved shirt and pants, chemical-resistant gloves and a self-contained breathing apparatus.

For cleaning following ventilation, wear chemical-resistant coveralls over a long-sleeved shirt and pants, chemical-resistant gloves and a suitable respirator.

For tasks other than cleaning following ventilation, wear cotton coveralls and chemical-resistant gloves.

RESTRICTED-ENTRY INTERVAL (REI):

Do not allow entry into treated areas (to attend to fans, etc.) until after two (2) hours of mechanical ventilation (fans should circulate outside air) or four (4) hours of passive ventilation (windows, vents and doors should be opened). If visible aerosol remains after these periods, do not enter until the aerosol has settled.